The Regulation and Quality Improvement Authority

RQIA Provider Guidance 2024-2025

Independent Health Care

Fertility Services and Assisted Conception

What we do

The Regulation and Quality Improvement Authority (RQIA) is the independent body that regulates and inspects the quality and availability of Northern Ireland's health and social care (HSC) services. We were established in 2005 under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 to drive improvements for everyone using health and social care services.

Through our programme of work, we provide assurance about the quality of care; challenge poor practice; promote improvement; safeguard the rights of service users; and inform the public through the publication of our reports. RQIA has four main areas of work:

- We register and inspect a wide range of independent and statutory health and social care services.
- We work to assure the quality of services provided by the Strategic Planning and Performance Group (SPPG), HSC trusts and agencies - through our programme of reviews.
- We undertake a range of responsibilities for people with mental ill health and those with a learning disability.
- We support establishments and service providers to improve the service they deliver.

All work undertaken by RQIA is focused on the following four domains:

- Is care safe?
- Is care effective?
- Is care compassionate?
- Is the service well led?

RQIA registers, inspects and supports a wide range of health and social care services. These include: nursing, residential care, and children's homes; domiciliary care agencies; day care settings/centres; independent hospitals; independent clinics; independent medical agencies; nursing agencies; residential family centres; adult placement agencies; voluntary adoption agencies, school boarding departments and young adult supported accommodation (inspected only).

The four domains

How we will inspect

We will inspect every fertility service at least annually. Our multi-disciplinary team of inspectors will carry out an unannounced inspection, and from time to time our inspectors may also carry out other inspections in response to concerns that may be raised with us.

When we inspect a fertility service, we aim to provide assurances in respect of the standard, quality and safety of services delivered. We do this by:

- Seeking the views of the people who use the service, or their representatives.
- Talking to the management and other staff on the day of the inspection.
- Examining a range of records including care records, incidents, complaints and policies.
- Providing feedback on the day of the inspection to the manager on the outcome of the inspection.
- Providing a report of our inspection findings and outline any areas for quality improvement.

Our inspections are underpinned by:

- The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003
- The Independent Health Care Regulations (Northern Ireland) 2005
- The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011
- The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2022
- The Department of Health, (DOH) Minimum Care Standards for Healthcare Establishments July 2014

Provider guidance in respect of the maintenance and upkeep of the premises and the management of medicines are also available on our website and are currently under review. These documents should be reviewed to ensure compliance with the minimum standards and legislation.

Should you have additional categories of care, please ensure that you review and adhere to the relevant provider guidance document i.e. Private Doctor (PD).

What we look for when we inspect

To help us to report on whether care is safe, effective, compassionate and well led, we will look for evidence against the following indicators.

Is care safe?

Avoiding and preventing harm to service users from the care, treatment and support that is intended to help them.

Indicator S1
There are, at all times, suitably qualified, competent and experienced persons working in the service in such numbers as are appropriate for the health and welfare of service users.

Examples of evidence

Staffing

- There are sufficient numbers of staff in various roles to fulfil the needs of the establishment and patients.
- There are arrangements in place for maintaining a record of the shifts worked by each staff member to include a record of the hours worked by each person.
- There is an induction programme in place appropriate to the role.
- A system is in place to ensure all staff receive appropriate training to fulfil the duties of their role in keeping with professional body continuing professional development (CPD) requirements and RQIA training guidance.
- A system is in place to ensure staff receive annual appraisal and records are retained.
- There are arrangements in place for monitoring the registration status for all clinical staff e.g. General Medical Council (GMC), Nursing and Midwifery Council (NMC); records should be retained for inspection.
- There are arrangements in place for monitoring the professional indemnity of all clinical staff who require individual indemnity cover; records should be retained.
- All practitioners have the necessary training, qualifications, experience and expertise to safely and competently undertake the treatments and services they offer.
- Evidence that each private doctor has confirmation of identity, current GMC registration, professional indemnity insurance, qualifications in line with service provided, evidence of ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and GMC.
- Evidence that each private doctor has an appointed responsible officer (RO).
- Arrangements are in place to link into the wider system of RO's for doctors with practising privileges who work in other parts of the Northern Ireland (NI) healthcare system or in other healthcare systems beyond NI.
- Arrangements are in place to ensure that any newly appointed private doctor has notified their aligned RO of their new position.
- Evidence of arrangements for revalidation.
- The private doctor is aware of their responsibilities under GMC Good medical practice 2024 and 'Good practice in prescribing and managing medicines and devices'.
- Arrangements are in place to ensure the full appraisal document for each medical practitioner is reviewed and scrutinised by the registered person before granting or renewing practising privileges and a record retained.

Recruitment and selection

- Staff have been recruited in line with Regulation 19 (2) Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended.
- There is a written policy and procedure for staff recruitment in keeping with Regulation 19 (2) Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005.
- Staff personnel files are in keeping with 19 (2) Schedule 2, as amended.
- Enhanced AccessNI checks are received prior to all new staff commencing work.
- All staff involved in Regulated Activity with adults or Regulated Activity with children must have their enhanced AccessNI disclosure checked against the barred list in keeping with AccessNI code of practice.
- Recruitment and selection records should be retained for three years from the date of last entry in keeping with Regulation 21 (3) Schedule 3 Part II.
- An up to date staff register should be maintained and retained in keeping with Regulation 21 (3) Schedule 3 Part II.

Indicator S2
The service promotes and makes proper provision for the welfare, care and protection of service users.

Examples of evidence

Safeguarding - Adult

- Policies and procedures are in line with the regional Adult Safeguarding Prevention and Protection in Partnership policy (July 2015) and Northern Ireland Adult Safeguarding Partnership operational handbook June 2017 .
- The establishment has identified an adult safeguarding champion (if required).
- There is an identified safeguarding lead and staff are aware of who the safeguarding lead is.
- There are arrangements in place to embed into practice the regional adult safeguarding operational procedures.
- All staff receive the relevant level of training as outlined in RQIA training guidance.
- Staff should have training in keeping with the Northern Ireland Adult Safeguarding Partnership Training Strategy 2013 (revised 2016).
- Staff are knowledgeable about adult safeguarding and are aware of their obligations in relation to raising concerns.
- All suspected, alleged or actual incidents of abuse are fully and promptly referred to the relevant persons and agencies for investigation in accordance with procedures and legislation and written records must be retained.
- Where shortcomings are highlighted as a result of an investigation, learning arising should be assessed, implemented and quality assured.
- Staff are familiar with their responsibilities and know how to appropriately recognise poor practice and raise concerns.

Safeguarding - Children

- Policies and procedures are in line with the regional policy Co-operating to Safeguard Children and Young People in Northern Ireland, (August 2017) and Safeguarding Board for Northern Ireland (SBNI) Procedures Manual (November 2017).
- There is an identified safeguarding lead and staff are aware of who the safeguarding lead is.
- There are arrangements in place to embed into practice the regional procedures.
- All staff receive the relevant level of training as outlined in RQIA training guidance.

- Staff training should be in keeping with SBNI Child Safeguarding Learning and Development Strategy and Framework 2020 – 2023.
- Staff are knowledgeable about safeguarding children and are aware of their obligations in relation to raising concerns.
- All suspected, alleged or actual incidents of abuse are fully and promptly referred to the relevant persons and agencies for investigation in accordance with procedures and legislation and written records must be retained.
- Where shortcomings are highlighted as a result of an investigation, learning arising should be assessed, implemented and quality assured.
- Staff are familiar with their responsibilities and know how to appropriately recognise poor practice and raise concerns.

Indicator S3
There are systems in place to ensure that unnecessary risks to the health, welfare or safety of service users are identified, managed and where possible eliminated.

Examples of evidence

Management of patients undergoing fertility treatment

- There are a range of treatment protocols in place for the management of patients receiving assisted conception services which have been developed and agreed by all professionals within the establishment.
- There are systems in place to regularly review protocols and discuss patient outcomes.
- There is a protocol for the prevention and management of Ovarian Hyper Stimulation Syndrome (OHSS) which is evidence based and in line with best practice guidelines.
- There are written protocols in place for the close monitoring of patients in order to avoid unnecessary complications, including multiple pregnancies.
- There are up-to-date protocols setting out the number of embryos placed in a woman in any one cycle that comply with the Human Fertilisation and Embryology Authority (HFEA)'s code of practice.
- There are procedures for indelible labelling of material for individual patients to ensure the unique identification of a patient's material and records at all stages of treatment.
- There are clinical meetings involving the nurses, doctors and members of the embryology team to discuss the management of patients.

Resuscitation

- Policies and procedures in relation to the management of medical emergencies and resuscitation are in place (to include a risk assessment, training arrangements, provision of equipment, emergency medication, checking procedures, how to summon help, incident documentation and staff debriefing).
- Emergency medicines and equipment are available in accordance with British National Formulary (BNF) and the Resuscitation Council (UK)
- A robust system is in place for checking expiry dates of medicines and equipment by an identified individual.
- Medicines and equipment required for resuscitation or other medical emergencies are clearly defined, regularly monitored and records are maintained.
- These medicines and equipment are readily accessible in suitable packaging and available for use at all times.

- Resuscitation equipment is checked and restocked to ensure all equipment remains in working order and suitable for use at all times. Checks are carried out daily by a designated person and recorded.
- Resuscitation equipment is cleaned and decontaminated after each use.
- Management of medical emergencies and resuscitation is included in staff induction and update training is provided annually.
- Staff have knowledge and understanding of managing resuscitation and other medical emergencies.

Infection prevention control and decontamination procedures

- The environment is clean and clutter free.
- Infection prevention and control (IPC) policies and procedures are in place in keeping with The Northern Ireland Regional Infection Prevention and Control Manual.
- Records of training, which meet GMC, NMC recommendations are retained.
- Staff have knowledge of IPC measures in line with best practice, including the decontamination of equipment, commensurate with their role and responsibilities.
- The risk of cross infection to patients, staff and visitors is minimised by single use equipment or decontamination of reusable medical devices and equipment in line with manufacturer's instructions and current best practice.
- There are written guidelines for staff to make referrals for advice and support to infection control nurses, microbiology services and public health medical staff who have expertise in IPC.
- There is information available for IPC for patients, their representatives and staff.
- Exploration of any issues identified during inspection.

COVID-19

- Staff should have knowledge and understanding and adhere to the most up to date DoH guidance.
- Arrangements are in place to routinely review the websites listed below:
  Public Health Agency (PHA) Covid-19 webpage:
  https://www.publichealth.hscni.net/covid-19-coronavirus
  Northern Ireland (NI) direct Covid-19 webpage:
  https://www.nidirect.gov.uk/campaigns/coronavirus-covid-19

Risk management

- There are risk management procedures in place.
- All risks in connection with the establishment, treatment and services are identified, assessed and managed.
- Arrangements are in place to provide evidence of appropriate review of risk assessments.
- Any findings/learning arising from risk assessments should be implemented and assured.
- An overarching corporate risk register is in place which details the measures in place to mitigate and control identified risks.

Indicator S4
The premises and grounds are safe, well maintained and suitable for their stated purpose.

Examples of evidence

Environment

- There are dedicated rooms for specific purposes such as egg collection, production of semen specimens, treatment area for undertaking clinical procedures and laboratories for embryology procedures.
- The room used for egg collection and in-vitro fertilisation is close to the laboratory where fertilisation is to take place.
- There are secure designated areas with access by authorised personnel only for the atmospheric temperature controlled storages of gamete and embryos.
- The establishment is clean, clutter free, warm and pleasant.
- There are no obvious hazards to the health and safety of patients and staff.
- There are arrangements in place in relation to maintaining the environment (e.g. servicing of lift/gas/boiler/fire detection systems and fire-fighting equipment/fixed electrical wiring installation).
- Arrangements are in place to ensure that environmental risk assessments are reviewed on an annual basis.
- Any findings/learning arising from risk assessments should be implemented and assured.

Is care effective?

The right care, at the right time in the right place with the best outcome.

Indicator E1
The service responds appropriately to and meets the assessed needs of the people who use the service.

Examples of evidence

Management of patients

- Patient care records are contemporaneous and clearly outline the patient journey.
- Patient records include a record of consultation with the medical practitioner; consultation with other health care professionals; signed consent forms; patient care plans; patient treatment plans; embryology records; patient medical regime; and other relevant records.
- There are documented clinical meetings involving the nurses, doctors and members of the embryology team, to discuss the management of patients.
- The registered manager provides a weekly director's report to the Board of Directors, outlining the number of patient treatment cycles undertaken and any other issues.

Records

- Arrangements are in place for maintaining and updating clinical records.
- Record keeping is in accordance with legislation, standards and best practice guidance GMGR records management.
- A record keeping policy and procedure is available which includes the arrangements in respect of the creation, storage, recording, retention and disposal of records, and data protection.
- Records are securely stored (electronic and hard copy).

- The establishment is registered with the Information Commissioners Office (ICO).
- There are systems in place to audit the completion of clinical records and an action plan is developed to address any identified issues.
- Staff display a good knowledge of effective records management.
- The establishment has arrangements in place to comply with the General Data Protection Regulation (GDPR).
- A patient register in keeping with Schedule 3 Part II of the Independent Health Care Regulations (Northern Ireland) 2005 is maintained and kept-up to date.

Indicator E2
There are arrangements in place to monitor, audit and review the effectiveness and quality of care delivered to service users at appropriate intervals.

Examples of evidence

- A range of audits, including clinical audits are undertaken routinely and actions identified for improvement are implemented into practice.
- Arrangements are in place to escalate shortfalls identified during the audit process through the establishment's governance structures.

Indicator E3
There are robust systems in place to promote effective communication between service users, staff and other key stakeholders.

Examples of evidence

Patient information and decision making

- The establishment has written information available for prospective patients regarding the services provided, how to access these and the costs of treatment. This information is written in plain English and when required is available in an alternative language or format.
- There is a range of information leaflets on each procedure carried out by the establishment and given to patients on consultation, to enable them to make informed decisions regarding their treatment.
- During the consultation period the procedures, risks, complications and expected outcomes are discussed with each patient.
- There is a comprehensive range of standard operating procedures, protocols and clinical guidelines in place. These guidelines relate to all areas of the provision of safe, effective, patient centred care and adhere to the HFEA Code of Practice and other national best practice guidelines.
- All publicity materials used by the establishment conform to the guidelines of the GMC guidance document Good medical practice 2024 and the code of the NMC.
- There is a policy and procedure for ensuring that written information provided to patients seeking treatment identifies known risks and how confidentiality is ensured.
- There is a website for the establishment that provides information on the services available.
- Arrangements are in place for effective communication with other relevant healthcare professionals regarding patient care.
- The procedure for delivering bad news to patients their families and other significant people is developed in accordance with guidance such as Breaking Bad News regional guidelines 2003.
- There is an open and transparent culture that facilitates the sharing of information.
- Patients are aware of who to contact if they want advice or have any issues/concerns.
- Staff meetings are held on a regular basis and minutes retained.

- Staff can communicate effectively.
- Learning from complaints/incidents/near misses is effectively disseminated to staff, implemented and assured.

Is care compassionate?

Service users are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

Indicator C1
There is a culture/ethos that supports the values of dignity and respect, independence, rights, equality and diversity, choice and consent of service users.

Examples of evidence

Dignity, respect and rights

- Staff can demonstrate how confidentiality is maintained.
- Staff can demonstrate how consent is obtained.
- There is a policy and procedure on obtaining informed consent in line with DoH guidance on consent treatment and care.
- There is a suitable location for private consultation.
- There are arrangements in place to assist patients with a disability or who require extra support.
- There is a policy and procedure on maintaining confidentiality which is regularly assured.
- Patients' privacy and dignity is respected at all times.
- Patients' rights to make decisions about care and treatment are acknowledged and respected.
- Patients and visitors are treated and cared for in accordance with legislative requirements for equality and rights.
- The service facilities and layout of the establishment are designed to ensure the privacy and protection of confidentiality of people seeking treatment.
- Patients are reassured by the certificate of registration being displayed in a conspicuous place.

Mental capacity

- There are systems and processes in place to identify where there may be evidence of lack of mental capacity.
- There is a model of consultation, which facilitates an assessment of capacity in line with legal expectations.

Indicator C2
Service users are listened to, valued and communicated with, in an appropriate manner.

Examples of evidence

- There are arrangements in place to support patients to make informed decisions.
- There are arrangements for providing information in alternative formats/interpreter services, if required.

Counselling

- Counselling and support services are offered to all patients before, during and after treatment.

- There is information for patients on local and national counselling and support organisations.
- There are clear referral arrangements to specialist genetic counselling, when required.

Indicator C3
There are systems in place to ensure that the views and opinions of service users, and or their representatives, are sought and taken into account in all matters affecting them.

Examples of evidence

Patient consultation

- Patient consultation (patient satisfaction survey) about the standard and quality of care and environment is carried out at least on an annual basis.
- The results of the consultation are collated to provide a summary report.
- The summary report is made available to patients and a subsequent action plan is developed to inform and improve services.
- RQIA staff/patient questionnaire responses are reviewed and used to improve services.

Is the service well led?

Effective leadership, management and governance which creates a culture focused on the needs and the experiences of service users in order to deliver safe, effective and compassionate care.

Indicator L1
There are management and governance systems in place to ensure the overall quality and safety of services provided.

Examples of evidence

Governance arrangements

- Where the entity operating the establishment is a corporate body or partnership or an individual owner who is not in day to day management of the establishment, in accordance with Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005, arrangements are in place to ensure the registered person/nominated representative monitors the quality of services and undertakes an unannounced visit to the premises at least six monthly and produces a report of their findings (where appropriate).
- There are arrangements in place for policies and procedures to be reviewed at least every three years.
- Policies are centrally indexed, a date of implementation and planned review is recorded and they are retained in a manner which is easily accessible by staff.
- Arrangements are in place to provide evidence of an appropriate review of risk assessments e.g. legionella, fire, Control of Substances Hazardous to Health (COSHH).
- The registered person/s ensures that the establishment delivers a safe and effective service in line with the legislation, other professional guidance and minimum standards.
- Arrangements are in place in relation to medical governance in accordance with the GMC guidance document: Effective clinical governance for the medical profession: A handbook for organisations employing, contracting or overseeing the practice of doctors'.
- There are clear clinical governance structures in place.

Complaints

- The establishment has a complaints policy and procedure in accordance with the relevant legislation and DoH Guidance in relation to the Health and Social Care Complaints Procedure (Updated April 2023).
- Records are kept of all complaints and these include details of all communications with complainants, investigation records, the result of any investigation, the outcome and the action taken.
- Staff know how to receive and deal with complaints.
- Arrangements are in place to audit complaints to identify trends and improve services provided.
- Themes emerging from complaints are analysed with input from the Medical Advisory Committee (MAC) and other relevant governance committees and any themes identified are disseminated to all staff.
- Complaints are triaged to identify if there are any clinical issues which need to be further reviewed in line with risk management procedures.

Statutory notification of incidents and deaths to RQIA

- The establishment has an incident policy and procedure in place which includes reporting arrangements to RQIA.
- Incidents are effectively documented and investigated in line with legislation.
- All relevant incidents are reported to RQIA and other relevant organisations in accordance with legislation and procedures RQIA Statutory Notification of Incidents and Deaths.
- Arrangements are in place to audit adverse incidents to identify trends and improve service provided.

Equality

- The management have systems in place to consider equality for patients.

Indicator L2
There are management and governance systems in place that drive quality improvement.

Examples of evidence

Quality improvement

- There is evidence of a systematic approach to the review of available data and information, in order to make changes that improve quality, and add benefit to the organisation and patients.

Quality assurance

- Arrangements are in place for managing relevant alerts.
- Arrangements are in place for staff supervision and appraisal.
- There is collaborative working with external stakeholders e.g. General Practitioner (GP), multi-professional team.
- There are procedures to facilitate audit, including clinical audit (e.g. records, incidents, accidents, complaints).
- Results of audits are analysed and actions identified for improvement are embedded into practice.

- The registered person/s has arrangements in place for managing identified lack of competency and poor performance for all staff including those with practicing privileges, and reporting incompetence in line with guidelines issued by DoH and professional regulatory bodies.
- The registered person/s ensures that professional registration and revalidation requirements are met.

Indicator L3
There is a clear organisational structure and all staff are aware of their roles, responsibility and accountability within the overall structure.

Examples of evidence

- There is a defined organisational and management structure that identifies the lines of accountability, specific roles and details responsibilities of all areas of the service.
- Staff are aware of their roles and responsibilities and actions to be taken should they have a concern.
- The registered person/s have an understanding of their roles and responsibilities under legislation.
- Patients are aware of roles of staff within the establishment and who to speak to if they need advice or have issues/concerns.
- The registered person/s is kept informed regarding the day to day running of the establishment.
- There are opportunities to raise staff awareness through training and education regarding equality legislation to recognise and respond to patients' diverse needs.

Medical Advisory Committee (MAC)

- There are written terms of reference for the MAC.
- The MAC meets quarterly as a minimum, and arrangements are in place for extraordinary meetings, as necessary.
- The MAC reviews information collated by the registered manager on adverse clinical incidents (broken down by speciality, procedure and by clinical responsibility) on a quarterly basis to include:

    - All deaths
    - All unplanned re-admissions
    - Adverse incidents
    - All unplanned transfers to other hospitals or clinics
    - Other relevant clinical incidents
    - Complaints and compliments

- The MAC advises on corrective action when necessary.
- The MAC advises the service on developments in clinical practice.
- The MAC assists the senior management team to assure and evidence safe practice.
- The MAC provides the expertise to discuss and if necessary challenge practice of individual medical practitioners.
- Minutes of MAC meetings accurately reflect discussions progressed, actions agreed and persons responsible for taking forward actions within agreed timescales.

Practising privileges

- There is a written agreement between the medical practitioner and the establishment that sets out the terms and conditions of granting practising privileges.
- Practising privilege agreements are reviewed at least every two years.
- There is a written procedure that defines the process for application, granting, maintenance and withdrawal of practising privileges.

Indicator L4
The registered person/s operates the service in accordance with the regulatory framework.

Examples of evidence

- The statement of purpose and patient guide are kept under review, revised when necessary and updated.
- Insurance arrangements are in place for public and employer's liability.
- Registered person/s respond to regulatory matters (e.g. notifications, reports/QIPs, enforcement).
- Any changes in the registration status of the service are notified to RQIA.
- The RQIA certificate of registration is on display and reflective of services provided.

Indicator L5
There are effective working relationships with internal and external stakeholders.

Examples of evidence

- Arrangements are in place for staff to access their line manager.
- There are arrangements in place to support staff (e.g. staff meetings, appraisal & supervision).
- There are good working relationships and management are responsive to suggestions/concerns.
- There are arrangements for management to effectively address staff suggestions/concerns.
- There is a raising concerns/whistleblowing policy and procedural guidance for staff.

Inspection reports

Our inspection reports will reflect the findings from the inspection. Where it is appropriate, a Quality Improvement Plan (QIP) will detail those areas requiring improvement to ensure the service is compliant with the relevant regulations and standards as a minimum. Where either no areas for improvement result from the inspection this will be reflected in the report.

Once the inspection report is finalised and agreed as factually accurate, it will be made public on RQIA's website.

The Regulation and Quality Improvement Authority

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